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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/547,843	09/06/2005	Takashi Horiguchi	Q101074	9679

23373 7590 05/11/2007
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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05/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/547,843	Applicant(s) HORIGUCHI ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 11-16, 18-25 and 27-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/6/5; 5/16/6</u> | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment, two pages.</u> |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-10, 17 and 26, in the reply filed on April 27, 2007 is acknowledged.

Claims 11-16, 18-25 and 27-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 27, 2007.

Claims 1-10, 17 and 26 are under examination in the instant office action.

Claim Objections

2. Claims 3, 4, 10 and 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, claims 3, 10 and 17 depend from claim 1, which is limited to a protein of SEQ ID NO: 1, while claims 3, 10 and 17 encompasses partial peptides of SEQ ID NO: 1, which are of a broader scope than the base claim. Claim 4 is directed to a polynucleotide while it depends from claim 1, which is limited to the protein. Therefore, claims 3, 4, 10 and 17 can be infringed by a peptide or a polynucleotide, which does not infringe claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims fail to include any limitations which would distinguish the claimed proteins, peptides and polynucleotides from those which occur in nature. In the absence of the hand of man, naturally occurring nucleic acid molecules and proteins are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment of the claims to recite a purity limitation, if supported by the specification, is suggested to obviate this rejection. Applicant should point to the basis in the specification for any amendment to the claims.

5. Claims 1-10, 17 and 26 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

It is clear from the instant application that the protein described therein is what is termed an "orphan protein" in the art. The DNA of the instant application has been isolated because of

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its similarity to a known DNA. There is little doubt that, after complete characterization, this DNA and encoded protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediate obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion".

The instant claims are drawn to an isolated nucleic acid molecule and the protein encoded thereby of as yet undetermined function or biological significance. Specifically, the present invention relates to "a prophylactic/therapeutic agent for a neurodegenerative disease, [and] a β -amyloid production inhibitor" (p. 1 of the specification), and is based on the hypothesis that "a target gene for creating a medicine for neurodegenerative diseases can be found in genes participating in endoplasmic reticulum stress response" (p. 2 of the specification). The instant specification explains that the claimed polynucleotide of SEQ ID NO: 2 and encoding protein C1

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of SEQ ID NO: 1 (p. 64 of the instant specification) were identified by “exhaustive analysis of gene expression in nerve cells against endoplasmic reticulum stress” (top at p. 2). The specification further asserts that “[t]he protein of the present invention regulates repair and decomposition of abnormal proteins, neuronal death, amyloid production, etc. because its expression is increased upon application of endoplasmic reticulum stress to nerve cells” (p. 30). The examples using rat primary nerve cells show changes in C1 gene expression in response to different experimental conditions, pp. 65-67. The instant specification does not disclose biological role of C1 protein of SEQ ID NO: 1, its relevance to any specific physiological process or clinical condition, and fails to provide any scientific reasoning to support a statement that genes “participating in endoplasmic reticulum stress response” have a specific significance during neurodegeneration.

In the absence of knowledge of the biological significance of this specific nucleic acid and encoded protein, there is no immediately obvious patentable use for the polynucleotide or the encoded protein. According to the specification of the instant application, “where the DNA encoding the protein of the present invention is abnormal or deficient, or where the expression level of the protein of the present invention is reduced, there occur a variety of diseases, for example, neurodegenerative diseases” (p. 30, lines 13-20 of the instant specification). The instant specification fails to provide any evidence or sound scientific reasoning that would support a conclusion that the instant nucleic acid or encoded protein is associated with any diseases or disorder. To employ the DNA and the protein in the future methods of treatment by administration of pharmaceuticals comprising the claimed protein or DNA is not a “real world” because it would eventually relate to a protein for which no biological function is known. The

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instant application also fails to demonstrate use of the protein as a marker for any disease or condition (which would be a real world use). Because the instant specification does not teach a biological activity of the protein, which supports a practical utility, one would not reasonably believe that the administration of the claimed peptide would prevent or treat a condition or disease, like Alzheimer's disease, Parkinson's disease, Down's syndrome, Huntington's disease or any other neurodegenerative disease (see p. 30), as implied by the specification. To employ a nucleic acid of the instant invention in any of the disclosed methods would clearly be using it as the object of further research, which has been determined by the courts to be a utility, which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the encoded protein in their currently available form, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims -10, 17 and 26 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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8. Claims 8-9 are further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 8 and 9 encompass a transformant transformed with the recombinant vector comprising a polynucleotide of SEQ ID NO: 2 and a method of producing a protein by culturing this transformant. The instant specification contemplates transgenic non-human mammals carrying the DNA of SEQ ID NO: 2; however, the current state of the art is such that production of transgenic animals is generally considered to be unpredictable. The instant specification fails to provide enough guidance for a skilled practitioner as how to practice the claimed transgenic non-human transformant or methods for manufacturing proteins by using a transgenic animal, and no working examples or reference how a similar transformant was practiced in prior art. As such, it would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to practice Applicant's invention as currently claimed.

9. Claims 1, 3-5, 7-10, 17 and 26 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 3-5, 7-10, 17 and 26 are directed to partial peptides of the protein of SEQ ID NO: 1, nucleic acids encoding these partial peptides and a protein which is substantially the same as the protein of SEQ ID NO: 1, which encompasses proteins with at least 85% homology to the

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protein of SEQ ID NO: 1 (p. 9 of the specification). The claims do not require that the polypeptides possess any particular conserved structure or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides and polynucleotides that is defined only by sequence identity. However, the instant specification fails to describe the entire genus of proteins and nucleic acids, which are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a nucleic acid molecule which encodes a protein which has the amino acid sequence of SEQ ID NO: 1. This nucleic acid molecule has a nucleic acid sequence of SEQ ID NO: 2. The claims are drawn to proteins and nucleic acid molecules having at least 85% homology with a particular disclosed sequence or to fragments of these particular disclosed sequences. Thus, the claims are not limited to a protein or a polynucleotide with a specific sequence. The claims only require the claimed molecules to share some degree of structural similarity to the protein of SEQ ID NO: 1 or to the polynucleotide of SEQ ID NO: 2. The specification only describes a polynucleotide of SEQ ID NO: 2 encoding a protein having the amino acid sequence of SEQ ID NO: 1 and fails to teach or describe any other protein which lacks the amino acid sequence of SEQ ID NO: 1 or polynucleotide lacking SEQ ID NO: 2, which have any relevance to protein C1.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making

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the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. As stated above, it is not even clear what region of the encoded polypeptide has the disclosed activity. The specification does not provide a complete structure of those proteins and nucleic acid molecules having at least 85% homology with a particular disclosed sequence or fragments of these particular disclosed sequences and fails to provide a representative number of species for the claimed genus. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 1 and polynucleotides comprising the nucleic acid sequence of SEQ ID NO: 2, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 9, 10, 17 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claims 9, 10 and 17 are vague and indefinite for recitation "the partial peptide or its salt thereof". The metes and bounds of the recited limitation cannot be determined from the claims or the instant specification. Because the limitation is indefinite, it is not obvious as what is intended by a method of recombinant production of a salt of the partial peptide. Clarification is required.

13. Claim 26 is indefinite for being dependent from indefinite claim.

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14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 3-5, 7-10, 17 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillman et al., 2000, WO20026245-A2.

Claims 3-5, 7-10, 17 and 26 encompass partial peptides of the protein of SEQ ID NO: 1 and partial polynucleotides of the polynucleotide of SEQ ID NO: 2. Document of Hillman et al. teaches a polypeptide, which is 83% identical with the instant protein of SEQ ID NO: 1, see a copy of a sequence alignment attached to the instant office action. Document of Hillman et al. further discloses recombinant production of the polypeptides and their use with respect to neurological disorders, see abstract and the whole document, thus, fully anticipating the instant claims 3-5, 7-10, 17 and 26.

Conclusion

16. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

May 7, 2007

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<!--StartFragment-->RESULT 2
AAY71071
ID  AAY71071 standard; protein; 222 AA.
XX
AC  AAY71071;
XX
DT  29-AUG-2000 (first entry)
XX
DE  Human membrane transport protein, MTRP-16.
XX
KW  Human; membrane transport protein; MTRP-16; antiinflammatory; cytostatic;
KW  antithyroid; immunosuppressive; thyromimetic; antidiabetic; nootropic;
KW  antidiarrheic; neuroprotective; antidepressant; nephrotropic; virucide;
KW  antihelminthic; protozoacide; antibacterial; neuroleptic; antigout;
KW  diagnosis; prevention; treatment; membrane transport disorder; epilepsy;
KW  Menkes disease; diabetes; Parkinson's disease; neurological disorder;
KW  Alzheimer's disease; depression; schizophrenia; immune disorder; allergy;
KW  inflammatory disorder; AIDS; Addison's disease; atherosclerosis; gout;
KW  Graves disease; Hashimoto's thyroiditis; microbial infection; cancer;
KW  cell proliferative disorder.
XX
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XX
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XX
PD  11-MAY-2000.
XX
PF  04-NOV-1999; 99WO-US026048.
XX
PR  04-NOV-1998; 98US-0172255P.
PR  24-NOV-1998; 98US-0172252P.
PR  22-DEC-1998; 98US-0172214P.
PR  26-FEB-1999; 99US-0121896P.
XX
PA  (INCY-) INCYTE PHARM INC.
XX
PI  Hillman JL, Yue H, Tang YT, Lal P, Corley NC, Guegler KJ;
PI  Baughn MR, Azimzai Y, Lu DAM;
XX
DR  WPI; 2000-365576/31.
DR  N-PSDB; AAD00615.
XX
PT  Novel human membrane transport proteins useful for diagnosis, prevention
PT  and treatment of membrane transport disorders, immune/inflammatory
PT  disorders and cell proliferative disorders including cancer.
XX
PS  Claim 1; Page 109; 136pp; English.
XX
CC  The present sequence is a membrane transport protein, MTRP-16 from Incyte
CC  clone 3657824 isolated from human ENDPNOT02 cDNA library. MTRP-16 shows
CC  homology to Escherichia coli cation transport protein and is expressed in
CC  cardiovascular, haematopoietic/immune and nervous tissues. The present
CC  sequence is useful in diagnosis, prevention and treatment of disorders
CC  related with increased or decreased expression of MTRP such as familial
CC  goitre, Menkes disease, diabetes, Parkinson's disease, neurological
CC  disorders such as Alzheimer's disease, depression, epilepsy,
CC  schizophrenia, immune/inflammatory disorders such as AIDS, Addison's
CC  disease, allergies, atherosclerosis, Graves disease, gout, Hashimoto's
CC  thyroiditis, viral, bacterial, fungal, parasitic, protozoal or helminthic
CC  infections and cell proliferative disorders such as cancer. Fragments of
CC  MTRP polynucleotides are useful as targets in microarrays. MTRP DNA is
CC  also useful for generating hybridisation probes useful in mapping genomic
CC  sequences and detecting differences in sequences among normal, carrier
CC  and affected individuals. It is also used for screening libraries of
CC  compounds in drug screening techniques
XX
SQ  Sequence 222 AA;

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Query Match 83.9%; Score 1198; DB 3; Length 222;
Best Local Similarity 100.0%; Pred. No. 7.8e-104;
Matches 222; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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